UNITED STATES DISTRICT COURT
FOR THE DISTRCIT OF MAINE

IRVIN FOURNIER,	)	**Case No.**
	)	
Plaintiff,	)	**DEMAND FOR JURY TRIAL**
	)	
vs.	)	
	)	
COOK INCORPORATED;	)	
	)	
COOK MEDICAL, LLC. and WILLIAM COOK EUROPE, APS,	)	
	)	
Defendants,	)	

COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL

COMES NOW Plaintiff IRVIN FOURNIER, by and through his undersigned attorney, and files this, Complaint for Damages and Demand for Jury Trial, against Defendants COOK INCORPORATED, COOK MEDICAL LLC, and WILLIAM COOK EUROPE APS (collectively the "Defendants") and alleges the following:

1. This is an action for damages relating to Defendants' development, testing, assembling, manufacture, packaging, labeling, preparing, distribution, marketing, supplying, and/or selling the defective product sold under the name "inferior vena cava filter" (hereinafter "IVC filter").

THE PARTIES

2. Plaintiff IRVIN FOURNIER, ("Plaintiff") at all times relevant to this action is a citizen of and resides in Wallagrass (Aroostook County), Maine.

3. Defendant Cook Incorporated is an Indiana Corporation with a principal place of business located at 750 Daniels Way, Bloomington, Indiana 47404. The registered agent for Cook Medical Incorporated is Corporation Service Company, 135 North Pennsylvania

St., Suite 1610, Indianapolis, IN 46204. Defendant Cook Incorporated is a citizen of Indiana.

4. Defendant Cook Incorporated is the parent company of Defendant Cook Medical LLC (f/k/a Cook Medical Incorporated). Defendant Cook Medical LLC is an Indiana Corporation with a principal place of business located at 400 Daniels Way, Bloomington, Indiana 47404. The registered agent for Cook Medical LLC is Corporation Service Company, 135 North Pennsylvania St., Suite1610, Indianapolis, IN 46204. Cook Medical LLC's members and principals are residents and citizens of Indiana.

5. Defendant William Cook Europe APS is a foreign corporation with its principal place of business located at Sandet 6, Bjaeverskov, Denmark and regularly conducts business in the State of North Carolina and is authorized to do so. Defendant also carried on solicitations or service activities in the state of Indiana. Defendant is both incorporated in and has its principal place of business in Denmark.

6. Hereinafter, each of the above Defendants shall be collectively referred to as "Cook."

7. At all times alleged herein, Defendants Cook include and included any and all parent companies, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

8. Cook develops, manufactures, sells and distributes medical devices for use in various medical applications including endovascular cardiology, and surgical products throughout the United States and around the world. Cook's products include the Cook

Günther Tulip and Celect Vena Cava Filters, which are used for the prevention of recurrent pulmonary embolism via placement in the vena cava.

9. This Court has jurisdiction over the subject matter of this action and the parties. This Court is also the proper venue for this action.

STATEMENT OF VENUE AND JURISDICTION

10. This cause of action is brought pursuant to diversity of citizenship between the parties, 28 USCA, Section 1332, with the controversy exceeding Seventy-Five Thousand Dollars ($75,000.00).

11. Venue is proper in this Court as a substantial part of the events or omissions giving rise to the claim occurred in Wallagrass, Maine and the Defendants regularly conduct business in this District.

FACTUAL BACKGROUND

12. Defendants design, research, develop, manufacturer, test, market, advertise, promote, distribute, and sell products that are sold to and marketed to prevent, among other things, recurrent pulmonary embolism via placement in the vena cava. Defendants' products include, the Cook Celect Vena Cava Filter and the Gunther Tulip Filter (collectively referred to herein as "Cook Filters"), which are introduced via a coaxial introducer sheath system.

13. Defendants sought Food and Drug Administration ("FDA") approval to market the Cook Filters and/or its components under Section 510(k) of the Medical Device Amendment.

14. Section 510(k) allows marketing of medical devices if the device is substantially equivalent to other legally marketed predicate devices without formal review for the safety

or efficacy of the said device. The FDA explained the difference between the 510(k) process and the more rigorous "premarket approval" process in an amicus brief filed with the Third Circuit in *Horn v. Thoratec Corp*., 376 F.3d 163, 167 (3d Cir. 2004):

> A manufacturer can obtain an FDA finding of "substantial equivalence" by submitting a premarket notification to the agency in accordance with section 510(k)…A device found to be 'substantially equivalent' to a predicate device is said to be "cleared" by FDA (as opposed to "approved" by the agency under a [premarket approval]). A pre-market notification submitted under 510(k) is thus entirely different from a [pre-market approval] which must include data sufficient to demonstrate that the device is safe and effective. (Emphasis in original).

15. In *Medtronic, Inc. v. Lohr*, 518 U.S. 470,478-79 (1996), the Supreme Court similarly described the 510(k) process, observing:

> If the FDA concludes on the basis of the [manufacturer's] §510(k) notification that the device is 'substantially equivalent' to a pre-existing device, it can be marketed without further regulatory analysis…The §510(k) notification process is by no means comparable to the [premarket approval] process; in contract to the 1,200 hours necessary to complete a PMA review, the §510(k) review is completed in average of 20 hours…Section §510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets process quickly.

16. An IVC filter, like the Cook Filters, is a device designed to filter blood clots (called "thrombi") that travel from the lower portions of the body to the heart and lungs. IVC filters may be designed to be implanted, either temporarily or permanently, within the vena cava.

17. The inferior vena cava is a vein that returns blood to the heart from the lower portion of the body. In certain people, and for various reasons, thrombi travel from vessels in the legs and pelvis, through the vena cava into the lungs. Often these thrombi develop in the deep leg veins. The thrombi are called "deep vein thrombosis" or DVT. Once the thrombi reach the lungs they are considered "pulmonary emboli" or PE. An IVC filter, like the Cook IVC Filters, is designed to prevent thromboembolic events.

18. The Cook Filters are retrievable filters.

19. The Cook Celect® Vena Cava Filter has four (4) anchoring struts for fixation and eight (8) independent secondary struts to improve self-centering and clot trapping.

20. The Gunther Tulip® Vena Cava Filter has a top hook and (4) anchoring struts for fixation and on each strut, it has a "flower" formation that is shorter than the strut where a wire piece branches out on each side of the strut forming an overall "flower" type formation on each strut.

21. At all times relevant hereto, the Cook Filters were widely advertised and promoted by the Defendants as safe and effective treatment for prevention of recurrent pulmonary embolism via placement in the vena cava. At all times relevant hereto, Defendants knew its Cook Filters were defective and knew that defect was attributable to the design's failure to withstand the normal anatomical and physiological loading cycles exerted *in vivo.*

22. A retrospective review of all Cook Gunther Tulip Filters and Cook Celect filters retrieved between July 2006 and February 2008 was performed. One hundred and thirty (130) filter retrievals were attempted but in 33 cases, the standard retrieval technique failed. The authors concluded that "unsuccessful retrieval was due to significant endothelialization and caval penetration" and that "hook endothelialization is the main factor resulting in failed retrieval and continues to be a limitation with these filters." O. Doody, et al.; "Assessment of Snared-Loop Technique When Standard Retrieval of Inferior Vena Cava Filters Fail" Cardiovasc Intervent Radiol (Sept 4, 2008 Technical Note).

23. A retrospective review of 115 patients who underwent Cook Celect IVC filter insertion between December 2005 and October 2007 was performed. While filter insertion was successful in all patients, the authors also concluded that "[f]ailed retrieval secondary to

hook endothelialization continues to be an issue with this filter." O. Doody, et al; Journal of Medical Imaging and Radiation Oncology "Initial Experience in 115 patients with the retrievable Cook Celect vena cava filter" 53 (2009) 64-68 (original article).

24. In a review of clinical data related to 73 patients who had Celect IVC filter implanted between August 2007 and June 2008, the authors found that the Celect IVC filter was related to a high incidence of caval filter leg penetration. Immediately after fluoroscopy-guided filter deployment in 61 patients, four filters (6.5%) showed significant tilt. Follow-up abdominal CT in 18 patients demonstrated filter related problems in 7 (39%), which included penetration of filter legs in 4 and fracture/migration of filter components in 1.

25. In a study of Gunther Tulip and Celect IVC filters implanted between July 2007 and May of 2009 reported by Cardiovascular Interventional Radiology electronically on March 30, 2011 and published by journal in April 2012, one hundred percent of the Cook Celect filters and Gunther Tulip filters imaged after 71 days of implant caused some degree of filter perforation of the venal caval wall. Durack JC, et al, Cardiovasc Intervent Radiol., "Perforation of the IVC: rule rather than the exception after longer indwelling times for the Gunther Tulip and Celect Retrievable Filters," 2012 Apr.; 35(2):299-308. Epub 2011 Mar 30. The authors concluded: "Although infrequently reported in the clinical literature, clinical sequelae from IVC filter components breaching the vena cava can be significant." Defendants knew or should have known that their IVC filters were more likely than not to perforate the vena cava wall.

26. This same study reported that tilt was seen in 20 out of 50 (40%) of the implanted Gunther Tulip and Celect IVC filters and all titled filters also demonstrated vena caval perforation. Defendants knew or should have known that their IVC filters were

more likely than not tilt and to perforate.

27. On July 19, 2019, another study published in the New England Journal of Medicine, of the effectiveness of all retrievable filters was conducted concerning 240 severely injured patients, the study concluded that placement of vena cava filters after major trauma did not result in a lower incident rate of pulmonary embolism than those who did not have a filter implanted.

28. The study used both Cook and Bard IVC filters, 117 patients received Bard Denali filters, and 5 received Cook Celect filters. The study was published with its results, including the following:

- An entrapped thrombus was found within the filter in almost 5% of the patients.
- Placement of the filter (within 72 hours after injury) did not result in a lower rate of pulmonary embolisms or death at 90 days which again is the very condition Cook told the FDA, physicians, and the public its filters were designed to prevent including the Gunther Tulip and the Celect Filter.

29. While not inclusive of all medical studies published during the relevant time period, the above references show that the Defendants failed to disclose to physicians, patients and/or Plaintiff that its Cook Filters were subject to breakage, tilt, inability of removal, and migration even though they knew or should have known the same was true.

30. At all times relevant hereto, the Defendants continued to promote the Cook Filter as safe and effective even when inadequate clinical trials had been performed to support long or short to safety and/or efficacy.

31. The Defendants concealed the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Cook Filters, as aforesaid.

32. The Cook Filters are constructed of Conichrome®.

33. The Defendants specifically advertise the Conichrome® construction of the filter as a frame which "reduces the risk of fracture."

34. The failure of the Cook Filters is attributable, in part, to the fact that the Cook Filters suffer from a design defect causing it to be unable to withstand the normal anatomical and physiological loading cycles exerted *in vivo*.

35. At all times relevant hereto, the Defendants failed to provide sufficient warnings and instructions that would have put Plaintiff and the general public on notice of the dangers and adverse effects caused by implantation of the Cook Filters, including, but not limited to the design's failure to withstand the normal anatomical and physiological loading cycles exerted *in vivo*.

36. The Cook Filters were designed, manufactured, distributed, sold and/or supplied by the Defendants, and were marketed while defective due to the inadequate warnings, instructions, labeling, and/or inadequate testing in light of Defendants' knowledge of the products' failure and serious adverse events.

37. That at all times relevant hereto, the officers and/or directors of the Defendants named herein participated in, authorized and/or directed the production and promotion of the aforementioned products when they knew or should have known of the hazardous and dangerous propensities of the said products, and thereby actively participated in the tortious conduct that resulted in the injuries suffered by the Plaintiff.

38. On or about June 18, 2015 Plaintiff was implanted with a Cook Celect IVC filter at Eastern Maine Medical Center, located in Bangor, Maine, implanted by Dr. Justin

Levine, MD, due to right lower extremity popliteal DVT and not being a candidate for anticoagulation.

39. On or about June 23, 2015, Plaintiff had a CT of his chest done to evaluate the possibility of a pulmonary embolism ("PE"). The scan revealed the presence of a PE despite the placement of the Celect filter.

40. Plaintiff is at risk for future Cook Filter fractures, migrations, perforations, and tilting, as well as future recurrent DVT and/or pulmonary embolism. He faces numerous health risks, including the risk of death. For the rest of Plaintiff's life, he will require on-going monitoring of his condition.

41. At all times relevant hereto the Cook Filter was widely advertised and promoted by the Defendants as a safe and effective treatment for prevention of recurrent pulmonary embolism via placement in the vena cava.

42. At all times relevant hereto, Defendants knew its Cook Filter was defective and knew that defect was attributable to the design's potential to obstruct normal vena caval blood flow.

43. The Defendants failed to disclose to physicians, patients, or Plaintiff that their Cook Filter could cause an increased right of post-implantation thrombosis, including acute DVT, or that removal of the device within a short time period is necessary to prevent the device from becoming irretrievable.

44. At all times relevant hereto, the Defendants continued to promote the Cook Filter as safe and effective even though the clinical trials that had been performed were not adequate to support long or short term efficacy.

45. The Defendants concealed the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Cook Filter, as aforesaid.

46. At all times relevant hereto the Defendants failed to provide sufficient warnings and instructions that would have put the Plaintiff and the general public on notice of the dangers and adverse effects caused by implantation of the Cook Filter, including, but not limited to the design's potential to create a risk of post-implantation thrombotic events due to obstruction of vena caval blood flow.

47. The Cook Filter was designed, manufactured, distributed, sold and/or supplied by the Defendants, and was marketed while defective due to the inadequate warnings, instructions, labeling, and/or inadequate testing in light of Defendants' knowledge of the products failure and serious adverse events.

48. That at all times relevant hereto, the officers and/or directors of the Defendants named herein participated in, authorized and/or directed the production and promotion of the aforementioned products when they knew or should have known of the hazardous and dangerous propensities of the said products, and thereby actively participated in the tortuous conduct that resulted in the injuries suffered by the Plaintiff.

FRAUDULENT CONCEALMENT

49. Any applicable statutes of limitation have been tolled by the knowing and active concealment and denial of material facts known by Defendants when they had a duty to disclose those facts. They have kept Plaintiff ignorant of vital information essential to the pursuit of his claims, without any fault or lack of diligence on Plaintiff's part, for the purpose of obtaining delay on Plaintiff's part in filing on their causes of action. Defendants' fraudulent concealment did result in such delay.

50. Defendants are estopped from relying on the statute of limitations defense because Defendants failed to timely disclose, among other things, facts evidencing the defective and unreasonably dangerous nature of the Cook Celect Vena Cava Filter.

51. The Defendants are and were under a continuing duty to disclose the true character, quality and nature of the device that was implanted in Plaintiff, but instead they concealed them. Defendants' conduct, as described in this complaint, amounts to conduct purposely committed, which Defendants must have realized was dangerous, heedless and reckless, without regard to the consequences or the rights and safety of Plaintiff.

52. Defendants expressly and impliedly warranted that the Cook IVC Filter was a permanent lifetime implant and downplayed the risks associated with migration, perforation, tilt, fracture and other risks relied upon by the Plaintiff to his detriment.

CORPORATE/VICARIOUS LIABILITY

53. At all times herein mentioned, each of the Defendants was the agent, servant, partner, aider and abettor, co-conspirator and/or joint venturer of each of the other Defendants herein and was at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and/or joint venture and rendered substantial assistance and encouragement to the other Defendants, knowing that their collective conduct constituted a breach of duty owed to the Plaintiff.

54. There exists and, at all times herein mentioned, there existed a unity of interest in ownership between certain Defendants and other certain Defendants such that any individuality and separateness between the certain Defendants has ceased and these Defendants are the alter ego of the other certain Defendants and exerted control over those Defendants. Adherence to the fiction of the separate existence of these certain Defendants as

entities distinct from other certain Defendants will permit an abuse of the corporate privilege and would sanction a fraud and/or would promote injustice.

55. At all times herein mentioned, Defendants, and each of them, were engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing and/or advertising for sale, and selling products for use by the Plaintiff. As such, each Defendant is individually, as well as jointly and severally, liable to the Plaintiff for Plaintiff's damages.

56. At all times herein mentioned, the officers and/or directors of the Defendants named herein participated in, authorized and/or directed the production and promotion of the aforementioned products when they knew, or with the exercise of reasonable care and diligence should have known, of the hazards and dangerous propensities of said products, and thereby actively participated in the tortious conduct that resulted in the injuries suffered by the Plaintiff.

COUNT ONE: NEGLIGENCE

57. Plaintiff repeats and re-alleges paragraphs 12-56 and incorporates each allegation into this Count, as if set forth at length, in its entirety.

58. At all times relevant to this cause of action, the Defendants COOK INCORPORATED, COOK MEDICAL LLC, and WILLIAM COOK EUROPE APS, were in the business of designing, developing, manufacturing, marketing and selling sophisticated medical devices, including the Cook Filter.

59. At all times relevant hereto, the Defendants COOK INCORPORATED, COOK MEDICAL LLC, and WILLIAM COOK EUROPE APS, were under a duty to act reasonably to design, develop, manufacture, market and sell a product that did not present a risk of harm or injury to the Plaintiff and to those people receiving the Cook Filter.

60. At the time of manufacture and sale of the Cook Filter, the Defendants COOK INCORPORATED, COOK MEDICAL LLC, and WILLIAM COOK EUROPE APS, knew or reasonably should have known the Cook Filter:

a. Was designed and manufactured in such a manner so as to present an unreasonable risk of fracture of portions of the device;

b. Was designed and manufactured so as to present an unreasonable risk of migration of the device and/or portions of the device;

c. Was designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body;

d. Was designed and manufactured so as to present an unreasonable risk of perforation and damage to the vena cava wall;

e. Was designed and manufactured so as to present an unreasonable risk of post-placement thrombotic events; and/or

f. Was designed and manufactured so as to present an unreasonable risk of irretrievability after a certain short indwelling period.

61. Despite the aforementioned duty on the part of the Defendants COOK INCORPORATED, COOK MEDICAL LLC, and WILLIAM COOK EUROPE APS, they committed one or more breaches of their duty of reasonable care and were negligent in:

a. Unreasonably and carelessly failing to properly warn of the dangers and risks of harm associated with the Cook Filter, specifically its incidents fracture, migration, perforation, post-placement thrombosis, irretrievability, and other failure;

b. Unreasonably and carelessly manufactured a product that was insufficient in strength or structural integrity to withstand the foreseeable use of normal placement within the human body;

c. Unreasonably and carelessly designed a product that was insufficient in strength or structural integrity to withstand the foreseeable use of normal placement within the human body;

d. Unreasonably and carelessly designed a product that increased the risk of further thrombosis or exacerbation of thrombotic events; and

e. Unreasonably and carelessly designed a product that presented a risk of harm to the Plaintiff and others similarly situated in that it was prone to fail and/or cause other serious complications.

62. As a direct and proximate result of the Defendants' negligence, as described herein, Plaintiff has suffered and will continue to suffer serious physical injuries, pain and suffering, mental anguish, medical expenses, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

WHEREFORE, the Plaintiff IRVIN FOURNIER demands judgment against the Defendants COOK INCORPORATED, COOK MEDICAL LLC, and WILLIAM COOK EUROPE APS, for whatever amount he may be entitled, together with costs of this action.

COUNT TWO: NEGLIGENCE – FAILURE TO WARN

63. Plaintiff repeats and re-alleges paragraphs 12-62 in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

64. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the Cook Filter, including the one implanted into Plaintiff, into the stream of commerce and in the course of same, directly advertised and marketed the device to consumers or persons responsible for consumers.

65. At the time Defendants designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the device into the stream of commerce, Defendants knew or should have known the device presented an unreasonable danger to users of the product when put to its intended and reasonably anticipated use. Specifically, Defendants knew or should have known at the time they manufactured, labeled, distributed and sold the Cook Filter, which was implanted in Plaintiff, that the filter posed a significant risk of device failure.

66. Therefore, Defendants had a duty to warn of the risk of harm associated with the use of the device and to provide adequate instructions on the safe and proper use of the device. Defendants further had a duty to warn of dangers and proper safety instructions that it became aware of even after the device was distributed and implanted in Plaintiff.

67. Despite this duty, Defendants failed to adequately warn of material facts regarding the safety and efficacy of the Cook Filter, and further failed to adequately provide instructions on the safe and proper use of the device.

68. No health care provider, including Plaintiff's, or Plaintiff would have used the device in the manner directed, had those facts been made known to the prescribing healthcare providers and/or ultimate users of the device.

69. The health risks associated with the device as described herein are of such a nature that ordinary consumers would not have readily recognized the potential harm.

70. Plaintiff and Plaintiff's health care providers used the device in a normal, customary, intended, and foreseeable manner, namely as a surgically implanted device used to prevent pulmonary embolisms.

71. Therefore, the Cook Filter implanted in Plaintiff was defective and unreasonably dangerous at the time of release into the stream of commerce due to inadequate warnings, labeling and/or instructions accompanying the product.

72. The Cook Filter implanted in Plaintiff was in the same condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed and sold by Defendants.

73. As a direct and proximate result of Defendants' lack of sufficient warning and/or instructions, Plaintiff has suffered and will continue to suffer serious physical injuries, pain and suffering, mental anguish, medical expenses, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

WHEREFORE, Plaintiff IRVIN FOURNIER demands judgment against the Defendants COOK INCORPORATED, COOK MEDICAL LLC, and WILLIAM COOK EUROPE APS for whatever amount he may be entitled, together with costs of this action.

COUNT THREE: NEGLIGENCE – DEFECTIVE DESIGN

74. Plaintiff repeats and re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs 12-73 as though fully set forth herein.

75. At all times relevant to this action, Defendants developed, tested, designed, manufactured, inspected, labeled, promoted, distributed and sold into the stream of commerce the Cook Filter, including the one implanted in Plaintiff.

76. The Cook Filter was expected to, and did, reach its intended consumers without substantial change in the condition in which it was in when it left Defendants' possession. In the alternative, any changes that were made to Cook Filter implanted in Plaintiff were reasonably foreseeable to Defendants.

77. The Cook Filter implanted in Plaintiff was defective in design because it failed to perform as safely as persons who ordinarily use the product would have expected at the time of use.

78. The Cook Filter implanted in Plaintiff was defective in design, in that its risks of harm exceeded its claimed benefits.

79. The Defendants knew that safer alternative designs were available and would have prevented or significantly reduced the risk of the injury presented by Cook Filter and it was economically and technologically feasible at the time the filter left the control of the Defendants to prevent or reduce the risk of such a such a dangerous event by application of existing, reasonably achievable, scientific knowledge.

80. Plaintiff and Plaintiff's health care providers used the Cook Filter in a manner that was reasonably foreseeable to Defendants.

81. Neither Plaintiff, nor Plaintiff's health care providers could have by the exercise of reasonable care discovered the devices defective condition or perceived its unreasonable dangers prior to Plaintiff's implantation with the device.

82. As a direct and proximate result of the Cook Filter's defective design, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

83. At all times relevant hereto, the Cook Filter was dangerous and presented a substantial danger to patients who were implanted with the Cook Filter and these risks and dangers were known or knowable at the times of distribution and implantation in Plaintiff in 2008. Ordinary consumers would not have recognized the potential risks and dangers the Cook Filter posed to patients, because its use was specifically promoted to improve health of such patients. The Cook Filter was used by the Plaintiff and his treating physicians in a reasonably foreseeable manner.

84. The Defendants failed to provide warnings of such risks and dangers to the Plaintiff and his medical providers as described herein.

85. As a direct and proximate result of the Cook Filter's defects, as described herein, Plaintiff has suffered and will continue to suffer serious physical injuries, pain and suffering, mental anguish, medical expenses, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

WHEREFORE, Plaintiff IRVIN FOURNIER demands judgment against the Defendants COOK INCORPORATED, COOK MEDICAL LLC, and WILLIAM COOK EUROPE APS for whatever amount he may be entitled, together with costs of this action.

COUNT FOUR: NEGLIGENCE – MANUFACTURING DEFECT

86. Plaintiff re-alleges and incorporates by reference each and every allegation contained in paragraphs 12-85 as though fully set forth herein.

87. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the Cook Filter that was implanted into Plaintiff.

88. The Cook Filter implanted in Plaintiff contained a condition, which Defendants did not intend; at the time it left Defendants' control and possession.

89. Plaintiff and Plaintiff's health care providers used the device in a manner that was reasonably foreseeable to Defendants.

90. As a result of this condition, the product injured Plaintiff and failed to perform as safely as the ordinary consumer would expect when used in a reasonably foreseeable manner.

91. As a direct and proximate result of the Cook Filter's manufacturing defect, Plaintiff has suffered and will continue to suffer serious physical injuries, pain and suffering, mental anguish, medical expenses, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

WHEREFORE, Plaintiff IRVIN FOURNIER demands judgment against the Defendants COOK INCORPORATED, COOK MEDICAL LLC, and WILLIAM COOK EUROPE APS for whatever amount he may be entitled, together with costs of this action.

COUNT FIVE: BREACH OF IMPLIED WARRANTY

92. Plaintiff repeats and re-alleges each and every allegation in paragraphs 12-91 and incorporates each allegation into this Count, as if set forth at length, in its entirety.

93. Plaintiff, through his medical providers, purchased the Cook Filter from Defendants COOK INCORPORATED, COOK MEDICAL LLC, and WILLIAM COOK EUROPE APS.

94. At all times to this cause of action, the Defendants COOK INCORPORATED, COOK MEDICAL LLC, and WILLIAM COOK EUROPE APS were merchants of goods of the kind including medical devices and vena cava filters (like the Cook Filter).

95. At the time and place of sale, distribution and supply of the Cook Filter to Plaintiff, the Defendants expressly represented and warranted that the Cook Filter was safe, and impliedly warranted that the product was reasonably fit for its intended purpose and was marketable quality.

96. At the time of Plaintiff's purchase from Defendants, the Cook Filter was not in a merchantable condition, in that:

a. It was designed in such a manner so as to be prone to an unreasonably high incident of fracture, perforation of vessels and organs, and/or migration;

b. It was designed in such a manner so as to result in a unreasonably high incident of injury to the organs including the vena cava of its purchaser;

c. It was manufactured in such a manner so that the exterior surface of the Cook Filter was inadequately, improperly and inappropriately designed causing the device to weaken and fail;

d. It was designed in such a manner so as to increase the risk of post-placement thrombotic events; and

e. It was designed in such a manner so as to become irretrievable after a short period of indwelling time, causing increased risk of future failure and/or thrombotic events.

97. Additionally, implied warranties were beached as follows:

a. The Defendants failed to provide the warning or instruction and/or an adequate warning or instruction which a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the Cook Filter would cause harm;

b. The Defendants manufactured and/or sold the Cook Filter and that filter did not conform to representations made by the Defendant when it left the Defendant's control;

c. The Defendants manufactured and/or sold the Cook Filter that was more dangerous than an ordinary consumer would expect when used in an intended or reasonably foreseeable manner, and the foreseeable risks associated with the Cook Filter design or formulation exceeded the benefits associated with that design. These defects existed at the time the product left the Defendants' control; and

d. The Defendants manufactured and/or sold the Cook Filter when it deviated in a material way from the design specifications, formulas or performance standards or form otherwise identical units manufactured to the same design specifications, formulas, or performance standards, and these defects existed at the time the product left the Defendants' control.

98. Further, Defendants' marketing of the Cook Filter was false and/or misleading.

99. Plaintiff, through his attending physicians, relied on these representations in determining which IVC filter to use for implantation in the Plaintiff.

100. Defendants' filter was unfit and unsafe for use by users as it posed an unreasonable and extreme risk of injury to persons using said products, and accordingly Defendants breached their expressed warranties and the implied warranties associated with the product.

101. The foregoing warranty breaches were a substantial factor in causing Plaintiff's injuries and damages as alleged.

102. As a direct and proximate result of the Cook Filter's defects, as described herein, Plaintiff has suffered and will continue to suffer serious physical injuries, pain and suffering, mental anguish, medical expenses, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

WHEREFORE, the Plaintiff IRVIN FOURNIER demands judgment against the Defendants COOK INCORPORATED, COOK GROUP, INC., COOK MEDICAL LLC, and WILLIAM COOK EUROPE APS, for whatever amount he may be entitled, together with costs of this action.

COUNT SIX: NEGILENCE- MISREPRESENTATION

103. Plaintiff repeats and re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs 12-102 as though fully set forth herein.

104. At all times relevant to this cause, and as detailed *supra*, Defendants negligently provided Plaintiff, Plaintiff's health care providers, and the general medical community with false or incorrect information, or omitted or failed to disclose material information concerning the Cook Filter, including, but not limited to, misrepresentations relating to the following subject areas:

a. The safety of the Cook Filter;

b. The efficacy of the Cook Filter;

c. The rate of failure of the Cook Filter; and

d. The approved uses of the Cook Filter.

105. The information distributed by Defendants to the public, the medical community and Plaintiff's health care providers was in the form of reports, press releases, advertising campaigns, labeling materials, print advertisements, commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the Cook Filter. Defendants made the foregoing misrepresentations knowing that they were false or without reasonable basis. These materials included instructions for use and warning document that was included in the package of the Cook Filter that was implanted in Plaintiff.

106. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiff's health care providers; to gain the confidence of the public and the medical community, including Plaintiff's health care providers; to falsely assure them of the quality of the Cook Filter and its fitness for use; and to induce the public and the medical community, including Plaintiff's healthcare providers to request, recommend, prescribe, implant, purchase, and continue to use the Cook Filter.

107. The foregoing representations and omissions by Defendants were in fact false. The Cook Filter is not safe, fit, and effective for human use in its intended and reasonably foreseeable manner. The use of the Cook Filter is hazardous to the user's health, and said device has a serious propensity to cause users to suffer serious injuries, including without limitation, the injuries Plaintiff suffered.

108. In reliance upon the false and negligent misrepresentations and omissions made by Defendants, Plaintiff and Plaintiff's health care providers were induced to, and did use the Cook Filter, thereby causing Plaintiff to sustain severe and permanent personal injuries.

109. Defendants knew and had reason to know that Plaintiff, Plaintiff's health care providers, and the general medical community did not have the ability to determine the true facts intentionally and/or negligently concealed and misrepresented by Defendants, and would not have prescribed and implanted same, if the true facts regarding the device had not been concealed and misrepresented by Defendants.

110. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects in the form of dangerous injuries and damages to persons who are implanted with the Cook Filter.

111. At the time Defendants failed to disclose and misrepresented the foregoing facts, and at the time Plaintiff used the Cook Filter, Plaintiff and Plaintiff's health care providers were unaware of said Defendants' negligent misrepresentations and omissions.

112. Plaintiff, Plaintiff's health care providers and general medical community reasonably relied upon misrepresentations and omissions made by Defendants where the concealed and misrepresented facts were critical to understanding the true dangers inherent in the use of the Cook Filter.

113. As a direct and proximate result of the Plaintiff and Plaintiff's health care provider's reliance on the foregoing misrepresentations and omissions by Defendants, as described herein, Plaintiff has suffered and will continue to suffer serious physical injuries, pain and suffering, mental anguish, medical expenses, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

WHEREFORE, the Plaintiff IRVIN FOURNIER demands judgment against the Defendants COOK INCORPORATED, COOK MEDICAL LLC, and WILLIAM COOK EUROPE APS, for whatever amount he may be entitled, together with costs of this action. as described herein.

COUNT SEVEN: STRICT PRODUCTS LIABILITY – FAILURE TO WARN

114. Plaintiff repeats and re-alleges paragraphs 12-113 in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

115. Cook IVC Filters were defective and unreasonably dangerous when they left the possession of the Defendants in that they contained warnings insufficient to alert consumers, including Plaintiff of the dangerous risks associated with the subject product, including but not limited to the risk of tilting, perforation, fracture and migration which are associated with and did cause serious injury and/or death.

116. Information provided by Cook to the medical community and to consumers concerning the safety and efficacy of its IVC Filters did not accurately reflect the serious and potentially fatal adverse events Plaintiff could suffer.

117. At all times relevant hereto, the Cook IVC Filters were dangerous and presented a substantial danger to patients who were implanted with the Cook IVC Filters, and these risks and dangers were known or knowable at the times of distribution and implantation in Plaintiff. Ordinary consumers would not have recognized the potential risks and dangers the Cook IVC Filters posed to patients, because their use was specifically promoted to improve health of such patients.

118. Had adequate warnings and instructions been provided, Plaintiff would not have been implanted with Cook IVC Filters and would not have been at risk of the harmful

injuries described herein. The Defendants failed to provide warnings of such risks and dangers to the Plaintiff and their medical providers as described herein. Neither Plaintiff nor Plaintiff's physicians knew, nor could they have learned through the exercise of reasonable care, the risks of serious injury and/or death associated with and/or caused by Cooks' IVC Filters.

119. Defendants knew or had knowledge that the warnings that were given failed to properly warn of the increased risks of serious injury and/or death associated with and/or caused by Cook IVC Filters.

120. Plaintiff individually and through their implanting physicians, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

121. Defendants had a continuing duty to warn Plaintiff and his physicians of the dangers associated with the subject products.

122. Safer alternatives were available that were effective and without risks posed by Cooks' IVC Filters.

123. As a direct and proximate result of the Cook IVC Filters' defects, as described herein, Plaintiff suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost their ability to live a normal life, and will continue to be so diminished into the future. Furthermore, Plaintiff has lost earnings and will continue to lose earnings into the future and have medical bills, both past and future, related to his care because of the Cook IVC Filters' defects.

124. By reason of the foregoing, Defendants are liable to the Plaintiff for damages as a result of their failure to warn and/or adequately warn the Plaintiff and healthcare

professionals about the increased risk of serious injury and death caused by their defective IVC filters.

WHEREFORE, Plaintiff demands judgment against the Cook Defendants and seek damages as detailed in the Global Prayer of Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other an further relief as this Court deems just and proper.

COUNT EIGHT: STRICT PRODUCTS LIABILITY – DESIGN DEFECT

125. Plaintiff repeats and re-alleges paragraphs 12-124 in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

126. Defendants have a duty to provide adequate warnings and instructions for their products including their IVC Filters, to use reasonable care to design a product that is not unreasonably dangerous to users.

127. At all times relevant to this action, Defendants designed, tested, manufactured, packaged, labeled, marketed, distributed, promoted and sold their IVC Filters, placing the devices into the stream of commerce.

128. At all times relevant to this action, Cook's IVC Filters were designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed by Defendants in a condition that was defective and unreasonably dangerous to consumers, including Plaintiff.

129. Cook IVC Filters are defective in their design and/or formulation in that they are not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with their design and formulation.

130. Cook IVC Filters were expected to reach, and did reach, users and/or

consumers including Plaintiff without substantial change in the defective and unreasonably dangerous condition in which they were manufactured and sold.

131. Physicians implanted as instructed via the Instructions for Use and in a foreseeable manner as normally intended, recommended, promoted, and marketed by the Defendants. Plaintiff received and utilized Cook IVC Filters in a foreseeable manner as normally intended recommend, promoted, and marketed by the Defendants.

132. Cook IVC Filters were and are unreasonably dangerous in that, as designed, failed to perform safely when used by ordinary consumers, including Plaintiff including when the filters were used as intended and in a reasonably foreseeable manner.

133. Cook IVC Filters were and are unreasonably dangerous and defective in design or formulation for their intended use in that, when they left the hands of the manufacturers and/or supplier, they posed a risk of serious vascular and other serious injury which could have been reduced or avoided, inter alia, by the adoption of a feasible reasonable alternative design. There were safer alternative designs for the like products.

134. Cook IVC Filters were insufficiently tested and caused harmful adverse events that outweighed any potential utility.

135. Cook IVC Filters, as manufactured and supplied, were defective due to inadequate warnings, and/or inadequate clinical trials, testing, and study, and inadequate reporting regarding the results of the clinical trials, testing and study.

136. Cook IVC Filters, as manufactured and supplied, were defective due to its no longer being substantially equivalent to its predicate device with regard to safety and effectiveness.

137. Cook IVC Filters as manufactured and supplied by the Defendants are and

were defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of injuries from use and acquired additional knowledge and information confirming the defective and dangerous nature of its IVC Filters, Defendants failed to provide adequate warnings to the medical community and the consumers, to whom Defendants were directly marketing and advertising; and further, Defendants continued to affirmatively promote their IVC Filters as safe and effective and as safe and effective as their predicate device.

138. As a direct and proximate result of the Cook IVC Filters' defects, as described herein, Plaintiff has suffered permanent and continuous injuries, pain and suffering, disability, and impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost his ability to live a normal life and will continue to be so diminished into the future. Furthermore, Plaintiff has lost earnings and will continue to lose earnings into the future and has medical bills both past and future related to care because of the IVC filter's defect.

139. By reason of the foregoing, Defendants are liable to the Plaintiff for damages as a result of their failure to warn and/or adequately warn the Plaintiff and healthcare professionals about the increased risk of serious injury and death caused by their defective IVC filters.

WHEREFORE, Plaintiff demands judgment against the Cook Defendants and seek damages as detailed in the Global Prayer of Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other an further relief as this Court deems just and proper.

COUNT NINE: THE CASE FOR MEDICAL MONITORING

140. Plaintiff repeats and re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs 12-139 as though fully set forth herein.

141. In certain cases, medical monitoring is required to evaluate whether a Cook Filter (or portions of the Cook Filter) has fractured, tilted and/or migrated (collectively referred to herein as "device failure" or "failure"). In order to determine whether failure of the Cook Filter has occurred, imaging studies must be performed. Typically, these imaging studies will include un-enhanced computed tomography scan (CT Scan) so that the filter may be visualized. CT Scan imaging produces an image of the filter and is able to reveal whether the filter has fractured or migrated.

142. Patients requiring medical monitoring are recommended to undergo regular and frequent imaging studies of the device or portions of the device at least once or twice annually. As long as the device, or portions of the device, remains within the body of the patient, the potential for future device failure exists. Consequently, these patients require regular and frequent medical monitoring for the duration of time the device, or portions of the device, remain within their bodies.

143. Patients eligible for medical monitoring for the Cook Filter or portions of the device need not have experienced past failure of the Cook Filter. For example, patients who have undergone implant of the Cook Filter frequently learn that the Cook Filter cannot be removed due to the fact that it has "grown into" tissue, but, the fracture, tilt or migration of the device may not yet have occurred. As a result of the inability to remove the Cook Filter, the device must remain permanently implanted in the patient, for the patient's lifetime. Although these patients may not yet have experienced device failure, they are at risk for

future device failure and require regular and frequent monitoring to evaluate the integrity of the Cook Filter. In addition to the aforementioned imaging studies, endovascular intervention (typically cardiac catheterization) may also be used by medical professionals to diagnose or discover whether fractured portions of the Cook Filter System have migrated to the heart or lungs. Furthermore, endovascular surgery may assess the nature and extent of the damage resulting from failure of the Cook Filter.

144. In those instances where device fracture has occurred, and depending on the circumstances particular to the patient, a person may be required to undergo one or all of the following medical procedures:

a. CT Scanning or other imaging studies;

b. Cardiac Catheterization;

c. Open heart surgery;

d. Removal of the Cook Filter from the vena cava.

145. The Cook Filter was placed in Plaintiff's body on or about June 18, 2015. The Plaintiff subsequently suffered from a pulmonary embolism, despite the filter placement. Plaintiff also has good reason to believe his filter is no longer removable, as it has been in place for nearly 6 years. Plaintiff has incurred significant medical expenses and has endured physical pain and suffering, mental anguish, loss of enjoyment of life, and other losses, some of which are permanent in nature. Plaintiff is required to attend regular physicians' visits and to undergo imaging studies.

146. As a direct and proximate result of the conduct and defective product of the Defendants, as alleged in this Complaint, medical monitoring is necessary for Plaintiff. Medical monitoring includes.

a. Regularly scheduled CT scans or other appropriate imaging studies; and/or

b. Potential cardiac catheterization or other endovascular procedure to detect the presence of migrated pieces of the Cook Filter System; and/or Physicians' visits and examinations.

COUNT TEN: VIOLATIONS OF MAINE LAW PROHIBITING CONSUMER FRAUD AND UNFAIR AND DECEPTIVE TRADE PRACTICES

147. Plaintiff repeats and re-alleges paragraphs 12-146 in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

148. Defendants had a statutory duty to refrain from unfair or deceptive acts or practices in the sale and promotion of Cook's IVC Filters to Plaintiff.

149. Defendants engaged in unfair, unconscionable, deceptive, fraudulent and misleading acts or practices in violation of all states' consumer protection laws, identified below.

150. Through its false, untrue and misleading promotion of Cook's IVC Filters, Defendants induced Plaintiff to purchase and/or pay for the purchase of Cook's IVC Filters.

151. Defendants misrepresented the alleged benefits and characteristics of Cook's IVC Filters; suppressed, omitted, concealed, and failed to disclose material information concerning known adverse effects of Cook's IVC Filters; misrepresented the quality and efficacy of Cook's IVC Filters as compared to much lower-cost alternatives; misrepresented and advertised that Cook's IVC Filters were of a particular standard, quality, or grade that they were not; misrepresented Cook's IVC Filters in such a manner that later, on disclosure of the true facts, there was a likelihood that Plaintiff would have opted for an alternative IVC Filter or method of preventing pulmonary emboli.

152. Defendants' conduct created a likelihood of, and in fact caused, confusion and misunderstanding. Defendants' conduct misled, deceived, and damaged Plaintiff and Defendants' fraudulent, misleading, and deceptive conduct was perpetrated with an intent that Plaintiff rely on said conduct by purchasing and/or paying for purchases of Cook's IVC Filters. Moreover, Defendants knowingly took advantage of Plaintiff who were reasonably unable to protect their interests due to ignorance of the harmful adverse effects of Cook's IVC Filters.

153. Defendants' conduct was willful, outrageous, immoral, unethical, oppressive, unscrupulous, unconscionable, and substantially injurious to Plaintiff and offends the public conscience.

154. Plaintiff purchased Cook's IVC Filters primarily for personal, family, or household purposes.

155. As a result of Defendants' violative conduct in Maine, Plaintiff's resident state and where Plaintiff purchased and/or paid for purchases of Cook IVC Filters that were not made for resale.

156. Defendants engaged in unfair competition, or deceptive acts or practices in violation of 5 Me. Rev. Stat. Ann.§ 207 *et seq.*

WHEREFORE, Plaintiff demands judgment against the Cook Defendants and seeks damages as detailed in the Global Prayer of Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other an further relief as this Court deems just and proper; further,

COUNT ELEVEN: BREACH OF EXPRESS WARRANTY

157. Plaintiff repeats and re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs 12-156 as though fully set forth herein.

158. At all times to this cause of action, the Cook Defendants were merchants of goods of the kind including medical devices and vena cava filters (i.e., Cook IVC Filters).

159. At the time and place of sale, distribution and supply of the Cook IVC Filters to Plaintiff (and to other consumer and the medical community), the Defendants expressly represented and warranted in their marketing materials, both written and orally, and in the IFUs, that the Cook IVC Filters were safe, well-tolerated, efficacious, and fit for their intended purpose and were of marketable quality, that they did not produce any unwarned-of dangerous side effects, and that they were adequately tested.

160. At the time of Plaintiff's purchase from Defendants, the Cook IVC Filters were not in a merchantable condition and Defendants breached their expressed warranties, in that the filters:

a. were designed in such a manner so as to be prone to a unreasonably high incident of fracture, perforation of vessels and organs, and/or migration;

b. were designed in such a manner so as to result in a unreasonably high incident of injury to the organs of its purchaser; and

c. were manufactured in such a manner so that the exterior surface of the Cook Filters were inadequately, improperly and inappropriately designed causing the device to weaken and fail.

161. As a direct and proximate result of the Cook IVC Filters' defects, as described herein, Plaintiff has suffered permanent and continuous injuries, pain and suffering,

disability, and impairment. Plaintiff has suffered emotional trauma, harm, and injuries that will continue into the future. Plaintiff has lost his ability to live a normal life and will continue to be so diminished into the future. Furthermore, Plaintiff has lost earnings and will continue to lose earnings into the future and have medical bills both past and future related to care because of the IVC filters' defect.

162. Defendants expressly and impliedly warranted that the Cook IVC Filter was a permanent lifetime implant and downplayed the risks associated with migration, perforation, tilt, fracture and other risks relied upon by the Plaintiff to his detriment.

163. By reason of the foregoing, Defendants are liable to the Plaintiff for damages as a result of their breach express warranty.

WHEREFORE, Plaintiff demands judgment against the Cook Defendants and seeks damages as detailed in the Global Prayer of Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other an further relief as this Court deems just and proper; further,

COUNT TWELVE: PUNITIVE DAMAGES

164. Plaintiff re-alleges each and every allegation in paragraphs 12-163 and incorporates each allegation into this Count, as if set forth at length, in its entirety.

165. The actions and inactions of all the Defendants, and or alternatively the employees or agents of Defendants, and their predecessors-in-interest, whether taken separately, or together, were of such a character as to constitute a pattern or practice of intentional wrongful conduct and/or malice resulting in the injury and damages of Plaintiff.

166. More specifically, Defendants, or alternatively the employees or agents of Defendants, and their predecessors-in-interest, consciously and/or deliberately concealed

risks associated with their product and nevertheless proceeded with conscious indifference to the rights, safety, and welfare of Plaintiff by failing to act to disclose these risks to his or his healthcare professionals.

WHEREFORE, Defendants are guilty of oppression, fraud, willful and wanton conduct, and/or malice, express or implied for which they should be held liable in punitive damages to Plaintiff IRVIN FOURNIER.

TOLLING OF THE LIMITATIONS PERIOD

167. Defendants, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's healthcare providers the true and significant risks associated with Cook's IVC Filters.

168. As a result of Defendants' actions, Plaintiff and his prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that the Plaintiff had been exposed to the risks identified in this Complaint, and that those risks were the result of Defendants' acts, omissions, and misrepresentations.

169. Accordingly, no limitations period ought to accrue until such time as Plaintiff knew or reasonably should have known of some causal connection between Plaintiff being implanted with a Cook IVC Filter and the harm Plaintiff suffered as a result.

170. Additionally, the accrual and running of any applicable statute of limitations have been tolled by reason of Defendants' fraudulent concealment.

171. Additionally, Defendants are equitably estopped from asserting any limitations defense by virtue of their fraudulent concealment and other misconduct as described.

172. Additionally, the limitations period ought to be tolled under principles of equitable tolling.

REQUEST RELIEF

WHEREFORE, Plaintiff IRVIN FOURNIER prays for relief on the entire complaint, as follows: Judgment to be entered against all Defendants on all causes of action of this Complaint, including but not limited to:

173. Physical pain and suffering in the past and which, in reasonable probability, he will continue to suffer in the future;

174. Physical impairment and incapacity in the past and which, in reasonable probability, he will continue to suffer in the future;

175. Pain, suffering and mental anguish in the past and which, in reasonable probability, he will sustain in the future;

176. Reasonable and necessary medical expenses for treatment received in the past and, based upon reasonable medical probability, the reasonable medical expenses he will need in the future;

177. Disfigurement in the past and which, in reasonable probability, he will continue to suffer in the future;

178. Punitive damages;

179. Plaintiff be awarded full, fair, and complete recovery for all claims and causes of action relevant to this action;

180. Plaintiff be awarded all appropriate costs, fees, expenses, and pre-judgment and post judgment interest as authorized by law on the judgments entered in Plaintiff's behalf; and,

181. Such other relief the court deems just and proper.

JURY TRIAL

The Plaintiff respectfully requests a trial by jury in the above case as to all issues.

This 22 day of March 2021.

Respectfully Submitted,

s/ Susan Faunce
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